



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,899	03/08/2004	James M. Brugger	T4342-14198US21	1653
181 7590 11/25/2009 MILES & STOCKBRIDGE PC 1751 PINNACLE DRIVE SUITE 500 MCLEAN, VA 22102-3833				
EXAMINER				
WIEST, PHILIP R				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
11/25/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocketing@milestockbridge.com
sstiles@milestockbridge.com

Office Action Summary

Application No.

10/796,899

Applicant(s)

BRUGGER ET AL.

Examiner

Philip R. Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/09 has been entered.

Response to Amendment

In the reply filed 9/25/09, applicant amended claims 7 and 13 and added new claims 18-19. Claims 7-9 and 11-19 are currently pending.

Response to Arguments

Applicant's arguments with respect to the rejection(s) of claim(s) 7-9 and 11-17 under 102(b) as being anticipated by Polaschegg have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly considered prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 7-9 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth (US 5,188,604). Orth teaches an extracorporeal system comprising a blood treatment device 32, arterial and venous blood lines that convey blood to and from a patient access, a pump 28 configured to convey blood through the blood line, a pressure sensor 512 located directly upstream of the pump that senses pressure in the blood line, and a controller 44 connected to the pump and sensor, such that it receives a pressure signal from said sensor and controls the flow rate of the pump. The blood treatment device is connected directly downstream of the pump, such that the speed of the pump determines the pressure on the blood side of the filter (see Figure 1). Thus, the controller 44 has a programmed algorithm for maintaining constant arterial pressure, such that it is configured to maintain a constant pressure in the arterial blood line by regulating the speed of the pump in response to the sensed pressure, thereby maintaining a specific predetermined pressure range (Column 8, Lines 13-27). Regarding Claims 12 and 17, the controller is configured to reduce flow rate when the resistance to blood flow increases (i.e. the controller is configured to slow the flow rate when pressure drops, as per claims 8 and 14).

Orth teaches the system substantially as claimed, but does not specifically teach that the blood treatment device is a dialysis filter.

However, although the blood treatment device comprises a membrane-based oxygenator in the preferred embodiment, Orth clearly states that the blood treatment device 32 may be any blood treatment device that is well known in the art (Column 9, Lines 44-51). Additionally, Orth acknowledges that similar extracorporeal systems exist that remove blood from the body for oxygenation or for dialysis (Column 1, Lines 10-19). Orth's system provides controlled blood flow through the blood side of the extracorporeal system, such that the precise pressure on the blood side of the filter may be controlled. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to reconfigure the extracorporeal treatment system of Orth for use with a dialysis filter, so as to provide precise control over the pressure and flowrate of blood flowing across a dialysis filter, thereby controlling the exchange rate across the filter membrane.

2. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth in view of Cochran (US 4,739,492). Orth reasonably suggests the device substantially as claimed, but does not specifically describe the details of the dialysate side of the filter membrane. Cochran teaches a dialysis machine control system for ensuring that blood and dialysate are flowing at efficient rates and relative pressures. The dialysate side of the system comprises a waste line downstream of the filter membrane, said waste line comprising a pressure sensor 108 linked to a pump 102, such that spent dialysate is discharged through the fluid outlet at a controlled rate, thereby maintaining a desired fluid pressure on the dialysate side of the filter membrane

(Column 6, Lines 9-20 and Column 11, Lines 44-54). Specifically, the controller is configured to maintain a computed transmembrane pressure within the artificial kidney, thereby controlling mass transfer across the membrane (Column 11, Lines 44-54). Dialysate pressure control devices of this type are common in the art because they allow for automatic control of fluid pressures within a renal therapy device or other membrane-based blood treatment device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the extracorporeal treatment device of Orth with the dialysate line pressure control system of Cochran in order to provide accurate control over the transmembrane pressure, thereby providing an optimal mass transfer across the membrane.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
20 November 2009